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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,023	08/06/2001	Tor Regberg	PU-9843	6811

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EXAMINER
TELLER, ROY R

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,023	REGBERG ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to amendment, received 6/26/06, in which applicant has requested that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with an amendment. The request complies with 37 CFR 41.39(b)(1) and will be entered and considered. The request that prosecution be reopened will be treated as a request to withdraw the appeal.

Claims 1 and 3 have been amended. Claim 2 has been cancelled.

Claims 1 and 3-8 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation (MPEP 2164.01(a)). The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;

5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation. The claimed invention is drawn to a method for selectively enriching/removing a serum albumin from a mixture of other compounds by contacting said mixture with a ligand (=X). The ligand having affinity for and enabling binding of the serum albumin.

The instant specification discloses that 14 ligand structures, (pages 13-14), and 3 proteins, (page 14, lines 2-4) were tested for binding interaction. At page 16, lines 2-4, it is disclosed that based on conventional ways of interpreting the chromatogram recorded of the binding to a solid support comprising the ligands, , none of the ligand structures showed binding to IgG or HSA .Further, the instant specification recites that all chromatograms for IgG looked the same and the position of the eluted IgG suggested no interaction/binding (see page 16, lines 9-11). However, the specification further states that the inventors went further on and analyzed in more detail the shape and position of the peaks in the chromatogram (see page 16, lines 6-7). Ligands 1, 2, 5, 7, 10, 11,and 14 are said to show "retardation of the peaks", "two peaks in the flow through", "peaks with a shoulder", or "retarded peaks that were tailed" (see page 16, paragraph 2), but provided no actual data for consideration, merely these conclusory remarks. The specification provides no guidance as to what further steps were necessary to visualize the aforementioned details.

The specification provides no specific working examples of the claimed method of removing serum albumin from a mixture of other compounds using a ligand within the scope of the claims. At best, the specification only provides that ligand 11is able to weakly bind to HSA (which is not a mixture with other compounds) under specific binding and elution conditions (paragraph bridging pages 16-17), but does not demonstrate how this weak binding can be used in the claimed method of separating or enriching albumin from a complex mixture for this ligand let alone for ligands within the scope of the claims. That is, the specification does not disclose how to visualize the binding of a ligand to a mammalian serum albumin or how to use such binding to selectively remove or enrich albumin from a complex mixture. One skilled in the art would not have been able to determine whether any particular ligand selectively enriched or removed any serum albumin from a mixture of other compounds without undue experimentation.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Applicants arguments were carefully considered but were not found persuasive. Applicant points to experimental results on pages 16-17 of the instant specification. Specifically, as stated on page 16, structures 1-14 were tested for binding HSA in PBS at pH 7 and 7 structures (# 3, 4, 6, 8, 9, 12, and 13) showed an HSA peak located at the same elution volume and having the same shape. The other structures (# 1, 2, 5, 7, 10, 11, and 14) allegedly had an interaction with the media as evidenced from the shoulders and tailing of the peaks (not shown).

Applicant assert this demonstrates that such compositions are useful for enriching/ removing a serum albumin from a mixture of other compounds, and further, that such analyses of the chromatograms are known and practiced by those skilled in the art. However, the examiner contends that the applicant's instant specification did something not conventional in the art (see page 16, line 6). Applicant's brief states such analyses of the chromatograms are known and practiced by those skilled in the art, however, the instant specification states that based on conventional ways of interpreting the chromatogram recorded, none of the ligand structures showed binding to IgG or HSA. No adequate guidance is provided or explanation given, nor does the brief contain evidence to support how to use the invention because interaction is so weak the claimed method of separating or enriching albumin from a complex mixture cannot be practiced by one of ordinary skill in the art without undue experimentation.
For the above reasons, it is believed that the rejection should be sustained.

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
9/26/06

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600